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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,006	02/20/2002	Sarah Fredriksson	1003300-000909	4540
21839 7590 10/16/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER UNDERDAHL, THANE E	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 10/16/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Office Action Summary**

Application No.

10/069,006

Applicant(s)

FREDRIKSSON ET AL.

Examiner

Thane Underdahl

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7, 9, 10, 11, 12, 13 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 9, 10, 12, 13, 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

This Office Action is in response to the Applicant's request for continued examination received 8/6/07. Claims 1-4, 7, 9, 10-13, 16-20 are pending. Claims 11 and 20 are withdrawn. Claims 5-6, 8, 14-15, and 17 are cancelled. Claims 1, 4, 9, 10, 13 and 19 have been amended. No claims are new.

### **Response to Applicant's Arguments**

In the response submitted by the Applicant the 35 U.S.C § 102 (b) and 103 (a) rejection of the above claims based on Gordon (U.S. Patent # 4889120) are withdrawn in light of applicant's amendment.

### **New Rejections Necessitated by Amendment**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7, 9, 10, 12, 13, 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 uses the phrase "formation of temporary pores in said biological membrane". The phrase "temporary" is indefinite since it is unclear what is the transient nature of the pores. For example, are the pores only formed in the presence of the magnetic field and removed upon the removal of said field? Alternatively, are the temporary pores filled in time by the natural repair mechanism of the cell? Clarification is required. In the interest of compact

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prosecution, the term will include any pore or opening that appears and leaves the cell intact.

Claim 9 includes the phrase "specific lysis of biological membrane-enveloped structures". It is unclear what the specific lysis of the membrane-enveloped structures refers. For example, does this phrase refer to the lysis of a particular type of cell in a mixed population of cells.

Because claims 24, 7, 9, 10, 12, 13, 16-19 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Chang (U.S. Patent # 4822470).

These claims are drawn to a method for the introduction or extraction of exogenic bioparticles into or from biological membrane-enveloped structures (**BMES**). This method is accomplished by applying a magnetic alternating field to a sample of BMES

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to magnetically susceptible particles. The magnetic field causes temporary pores to form in the BMES to allow the ingress or egress of said particles. The BMES are selected from the group consisting of cells, bacteria, virus particles, and organelles at a subcellular level. The magnetic field is non-homogeneous and has an alternating gradient field direction. The bioparticles are selected from the group consisting of DNA molecules, RNA molecules, proteins, biopolymers, peptides, chemical preparations, organic compounds, inorganic compounds and synthetic polymers.

Chang teach a method of applying a continuous AC electrical field, which inherently contains an alternating field gradient that can form temporary pores in cells (Chang, Abstract and Col 6, 5-10). These pores allow the egress of magnetically susceptible particles such as DNA, RNA, enzymes, organic and inorganic compounds (Chang, Abstract). The DNA and RNA can be used to alter the genetic code of the BMES (Chang, col 3, lines 40-45).

Therefore the reference anticipates claims 1, 4, 7 and 10.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-4, 7, 9, 10, 12, 13, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent # 4822470) as applied to claims 1, 4, 7 and 10 above and for the following details.

The description and rejection of claims 1, 4, 7 and 10 are listed in the 35 U.S.C § 102(b) rejection above. Claims 2, 3, 12, and 13 limited the operating conditions of the method such as the frequency of the alternating field is 1-5 MHz and the field strength is 1mT. Claims 16 and 19 include the limitations of claims 7 and 10 into claim 2. Claims 9 and 18 limit the methods for the specific lysis of BMES.

While Cheng teaches a method of applying an AC magnetic field, which inherently contains an alternating field gradient, to induce pores in cells for the ingress of DNA and RNA to alter the genetic code of the BMS, they also teach that the frequency is in a range of 0.1 to 10 MHz. While this range does not anticipate the claimed range, M.P.E.P. § 2144.05 state:

"In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists."

Therefore the range taught by Cheng renders the range limited by the Applicant as obvious.

Also while Cheng does not teach the field strength of 1 mT, one of ordinary skill in the art would recognize that field strength is a result effective variables. Absent any teaching of criticality by the applicant concerning the field strength it would be *prima facie* obvious that one of ordinary skill in the art would recognize this limitation is a result effective variable which can be met as a matter of routine optimization (M.P.E.P. § 2144.05 II).

Also while Cheng does not teach the use of his method to lyse cells, it is clear from his disclosure that this is indeed possible. Chang teaches that if the applied field is above an induce potential,  $V_c$ , the membrane breakdown is irreversible and the pores will not reseal after the field is removed (Chang, col 7, lines 1-10). One of ordinary skill in the art would recognize from these teachings, that if the field is applied at sufficient intensities the membrane will irreversibly breakdown, the pores will not reseal and lyse as contents of the cell diffuse through the open pores of the broken membrane.

Therefore the references listed above renders obvious claims 1-4, 7, 9, 10, 12, 13, 16-19.

In summary no claims, as written, are allowed for this application.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure**, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

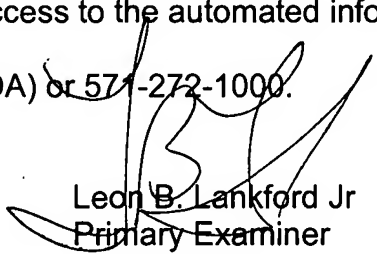
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272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl  
Art Unit 1651



Leon B. Lankford Jr  
Primary Examiner  
Art Unit 1651